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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,293	10/23/2000	Stephen T. Kuchn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/694,293

Applicant(s)

KUEHN ET AL.

Examiner

Victor X. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,10-13,18-20,23-26,28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,8,9,14,16,17,21,22,27 and 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,20,23-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,10-13,30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The request filed on 1/24/2007 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/694293 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-5,7,10-13 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 1 and 34, the disclosure does not describe at least **one arm of the pair of arms having a blind tapered slot** as recited. Clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,10 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Tener (2,470,327).

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Tener discloses in figures 1-3, a tool or a fastener having the limitations as recited in the above listed claims, as best understood including: one pair of arms 20,21, where at least one arm of the pair of arms has a tapered protrusion at 25 and the other arm has a blind tapered slot which occurs at slot 26 and where the arms pivot from one orientation to a gripping position and with the ends of the pair arms are directed toward each other at best seen in fig. 3. Regarding the intended use of the pair of arms for fastening two adjacent tissue heart valve leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Tener would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As to claims 30-35, Tener discloses in figures 1-3 a fastening member having the limitations as recited including: at cap 15, a gripper 10, where the cap is slidable relative to the gripper, where the gripper comprises a plurality of arms 20,21 radiates from a pivot 14 with at least a first arm having a spike at 25, where a second arm has a plurality of spikes at 24 such that a tapered slot at 26 is formed between the plurality of spikes, where the pivot is within an opening in the cap which is able to clock the arms in a collapsed gripping position.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-5,7,10-13 and 30-33 are rejected under 35 U.S.C. 102(3) as being unpatentable over Middleman et al (5,601,572).

Middleman et al disclose in Figs. 8-4c, a surgical instrument having the limitations as recited in claims 1 and 3, including: one pair of arms (21,23), where at least one arm of the pair of arms has at least a tapered protrusion along the curved at 29 that is capable for fastening two adjacent tissue heart valve leaflets, and where the arms pivot from one orientation to a gripping position which the paired arms being adjacent and directed toward each other at best seen in fig. 8-4a.

Middleman is silent that the other arm having a blind tapered slot. Instead, Middleman indicates that the device has a pair of arms 21,22 which is able to direct toward each other to at best seen in fig. 8-4a.

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to modify Middleman's device with an arm having a blind tapered slot because Applicant has not disclosed that provides the arm having a blind tapered slot an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Middleman device, and applicant's invention, to perform equally well with either the device taught by Middleman because both device would perform the same function of grasping by relative movement between the pair of arms.

Therefore, it would have been obvious to modify Middleman to obtain the invention as specified in the above claims because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Middleman. As to claims 4-5,7,10-13, a system further has a catheter or a cannula (25 or 159) that is inherently capable for deployment into a human heart, where the paired arms (21,23) extend toward each other when the fastener is in a gripping position, and where the arms flex to a low profile position to fit within the catheter, where the fastener further has a shaft that is releasably holding the fastener of the shaft

Regarding claims 30-33, Middleman et al disclose in Fig.8-9, where a fastening member comprises a cap (103 which is being slidable relative to a gripper (102), and where the gripper comprises a plurality of arms (102,106) from a pivot, where each arm has a spike (104), and where the cap comprises a locking mechanism to lock the gripper in a lock position (see fig. 8-9), and where the fastener further has a flexible rod (see fig. 8-7b) which has a disengaging mechanism which permits the rod to releasably holding the cap.

Allowable Subject Matter

5. Claims 18,20,23-26 and 28 are allowed.

The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses or suggests where a heart valve repair instrument comprising a cap that is located distal to the pivot and the pivot is located distal to a shaft, where a flexible rod connects to the cap to provide for movement of the cap relative to the pivot of the gripper and the shaft by pulling the flexible rod, where the cap has an opening that can be positioned over the pivot to lock the arms in a closed position.

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Response to Arguments

6. Applicant's arguments with respect to claims 1,30 have been considered but they are not persuasive. Applicant is asked to please refer to the modified prior art rejection above where examiner addresses applicant's concerns regarding prior art rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen
Examiner
Art Unit 3734



VN
3/27/2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER